Akebia Submits New Drug Application (NDA) to the FDA for Vadadustat for the Treatment of Anemia Due to Chronic Kidney Disease in Adult Patients on Dialysis and Not on Dialysis

March 30, 2021

CAMBRIDGE, Mass., March 30, 2021 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the treatment of anemia due to chronic kidney disease (CKD) in both adult patients on dialysis and adult patients not on dialysis.

"The submission of the vadadustat NDA for the treatment of anemia due to CKD in both adult patients on dialysis and not on dialysis marks a significant milestone not only for Akebia and our partners, but also for patients living with this disease," stated John P. Butler, Chief Executive Officer of Akebia. "The Akebia team and our collaborator, Otsuka, did an outstanding job preparing this comprehensive submission, which includes substantial data from over 8,000 patients across 36 clinical trials of vadadustat. We look forward to working with the FDA during the review process, and are excited to continue collaborating with our partners to advance vadadustat for the benefit of patients, subject to regulatory approval."

Based on standard FDA review timelines, the FDA has a 60-day period to determine whether the NDA is complete and acceptable for review. The Company's NDA submission did not include a Priority Review Voucher.

Otsuka Pharmaceutical Co. Ltd. (Otsuka) is working in close collaboration with Akebia to prepare a Marketing Authorization Application (MAA) for vadadustat for submission to the European Medicines Agency (EMA), expected this year.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. The Company was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vadadustat
Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH)
inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat recently completed its global Phase 3 clinical development program for the treatment of anemia due to CKD. Vadadustat is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). In Japan, vadadustat is approved and marketed under the tradename Vafseo™, as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Anemia due to Chronic Kidney Disease (CKD)
Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

Forward-Looking Statements
Statements in this press release regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements regarding: the potential for obtaining approval of vadadustat for the treatment of anemia due to CKD in both adult patients on dialysis and not on dialysis; the impact of the vadadustat NDA submission on Akebia, its partners and patients living with anemia due to CKD; the exact timing of the FDA's confirmation as to whether the NDA is complete and acceptable for review; and the timing of submission of an MAA for vadadustat to the EMA. The terms "expect," "continue," "look forward," "will," and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, but not limited to: any delays in acceptance and review of the NDA submission by the FDA for any reason, including the COVID-19 pandemic; the timing of regulatory filings, including the timing of filing the vadadustat MAA with the EMA; the direct or indirect impact of the COVID-19 pandemic on regulators and on Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; the potential therapeutic benefits, safety profile and effectiveness of vadadustat; the timing and content of advice given and decisions made by regulators, including the FDA and EMA; the potential indications, demand and market potential and acceptance of vadadustat; manufacturing, supply and quality risks; risks associated with hiring, training, management and retention and key personnel changes and transitional periods; the actual funding required to develop and commercialize vadadustat, and to operate Akebia; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for vadadustat, if approved; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its collaborations

partners and vendors; expected reliance on third parties, including with respect to the development, manufacturing, supply or commercialization of vadadustat, particularly if approved; Akebia's expectations, projections and estimates regarding its capital requirements; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 31, 2020 and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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